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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,009	09/15/2005	Jan Hall	21547-00299-US1	6978

30678 7590 02/19/2009

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EXAMINER	
REYNOLDS, STEVEN ALAN	
ART UNIT	PAPER NUMBER
3728	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,009	HALL, JAN	
	Examiner	Art Unit	
	Steven Reynolds	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *6-14 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 1/23/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 6-14 and 18-21 are withdrawn from consideration.

Claim Objections

2. Claim 4 is objected to because of the following informalities: In line 2, "container has been evacuated" should read "container is evacuated".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the container can be free from air (as presented in claim 1) and contain an inert gas (inert gases are present in the composition of air). Also, it is not clear how an inert gas, particularly argon, can be free from air when argon is present in the composition of air. For examination purposes,

Examiner assumes that the container is not free from air if an inert gas is present therein.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 5 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Betts et al. (US 5,230,427). Betts discloses an arrangement for a container capable of preserving the new-bone-forming effect of growth-stimulating substances (GS) applied to at least one implant product, the container being arranged so as, dependent on being acted upon, to allow access to at least one implant product with applied GS at the time of use of the at least one implant product with applied GS, wherein the container is capable of enclosing at least one implant product with applied GS in an environment which is essentially free from air, water and moisture.

Regarding the intended use of the claimed invention "for preserving the new-bone-stimulating substances (GS) applied to at least one implant product", it has been held that a recitation with respect to the manner in which a claimed apparatus is

intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. If the prior art structure is capable of performing the intended use, then it meets the claim. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Regarding claims 2, 3, 5 and 17, Betts discloses the container is in the form of a glass ampoule; the container is made of metal (the seal is made of metal) which makes the environment free from air, water and moisture possible; the container is evacuated to an internal pressure; and said environment comprises at least one essentially inert gas (argon).

7. Claims 1-3, 5 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilmot et al. (US 2003/0106824). Wilmot discloses an arrangement for a container (package 10 in combination with vial 30) capable of preserving the new-bone-forming effect of growth-stimulating substances (GS) applied to at least one implant product, the container being arranged so as, dependent on being acted upon, to allow access to the at least one implant product with applied GS at the time of use of the at least one implant product with applied GS, wherein the container is capable of enclosing at least one implant product with applied GS in an environment which is essentially free from air, water and moisture.

Regarding the intended use of the claimed invention "for preserving the new-bone-stimulating substances (GS) applied to at least one implant product", it has been held that a recitation with respect to the manner in which a claimed apparatus is

intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. If the prior art structure is capable of performing the intended use, then it meets the claim. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Regarding claims 2, 3, 5 and 17, Wilmot discloses the container is in the form of a glass ampoule (element 30); the container is made of metal (walls of package 12 are made from aluminum) which makes the environment free from air, water and moisture possible; the container is evacuated to an internal pressure; and said environment comprises at least one essentially inert gas (argon).

8. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoh (US 5,484,631). Hoh discloses an arrangement for a container capable of preserving the new-bone-forming effect of growth-stimulating substances (GS) applied to at least one implant product, the container being arranged so as, dependent on being acted upon, to allow access to the at least one implant product with applied GS at the time of use of the at least one implant product with applied GS, wherein the container is capable of enclosing at least one implant product with applied GS in an environment which is essentially free from air, water and moisture; and the container is made of metal (aluminum).

Regarding the intended use of the claimed invention "for preserving the new-bone-stimulating substances (GS) applied to at least one implant product", it has been held that a recitation with respect to the manner in which a claimed apparatus is

intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. If the prior art structure is capable of performing the intended use, then it meets the claim. *Ex parte Masham,* 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts et al. (US 5,230,427). As described above, Betts discloses the claimed invention except for the specific pressure of the container and the specific metal.

Regarding the specific pressure in the container, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the internal pressure any value, such as less than 1 mbar in order to have the desired effect

on the article, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding the specific metal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any metal such as stainless steel in order to have the desired strength. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

12. Claims 4, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilmot et al. (US 2003/0106824). As described above, Wilmot discloses the claimed invention except for the specific pressure of the container and the specific metal.

Regarding the specific pressure in the container, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the internal pressure any value, such as less than 1 mbar in order to have the desired effect on the article, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding the specific metal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any metal such as stainless steel in order to have the desired strength. It has been held to be within the general skill

of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoh (US 5,484,631). As described above, Hoh discloses the claimed invention except for the specific metal. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any metal such as stainless steel in order to have the desired strength. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Reynolds whose telephone number is (571)272-9959. The examiner can normally be reached on Monday-Friday 9:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. R./
Examiner, Art Unit 3728

/Mickey Yu/
Supervisory Patent Examiner, Art Unit 3728